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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,831	10/15/2001	Christophe Bonny	20349-512 (OTT-12)	4526

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/30/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/977,831

Applicant(s)

BONNY, CHRISTOPHE

Examiner

Padmashri Ponnaluri

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1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 15-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6, 8</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claims 1-35 are currently pending in this application.

1. Applicant's election without traverse of group VI, claim 14 in Paper No. 11, filed on 7/15/03 is acknowledged.
2. Claims 1-13, and 15-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.
3. Claim 14 is currently being examined in this application.
4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless

the references have been cited by the examiner on form PTO-892, they have not been considered.

5. Claim 14 is objected to because of the following informalities: the elected claim 14 of the instant invention is dependent on the non-elected claim 1. Applicants are requested to amend the claim such that the present claim is not dependent on non-elected invention.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

The instant claim briefly recites a method of translocating the transporter of peptide of claim 1 across the membrane of the pancreatic B-cells, wherein the transporter peptide is selected from the group consisting of SEQ ID NOS: 1-6.

The present claimed method uses transporter peptides of claim 1 (motif *a*) $X_mRX_oRX_n$). The instant claim recites transporter peptides of SEQ ID NOS: 1-6 which are used in translocating across the membrane of pancreatic B-cells. The specification discloses the peptides with SEQ ID OS: 1-6. The specification further discloses the peptides which are related to the

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specific motif RXXR of convertase consensus. The specification discloses that SEQ ID NO: 1 displayed by phage P1 is taken by the β TC-3 cells. The specification does not disclose the method of translocating a transporter peptide across the membrane of pancreatic B-cells. The specification disclosure does not disclose the use of peptides with SEQ ID NOS: 2- 6 in the claimed method. The specification description is directed to methods for identifying peptides from phage display library, which clearly do not provide adequate representation regarding the open ended method of instant claim. The instantly claimed method does not recite any method steps. And the specification does not recite a method of translocating the transporter peptide across the pancreatic B-cells.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that "written description of an invention involving a chemical genus, like a description a chemical species, 'requires precise definition, such as structure or formula or chemical name' of an the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1601 (Fed. Cir. 1993) [the claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA].

This holding is applicable to the present claimed method because the invention lacks showing of sufficient identifying characteristics or lacks examples of the transporter peptides of SEQ ID NOS: 2-6 in the claimed method, to demonstrate possession of claimed generic. Further the specification discloses that the transporter peptides share the convertase consensus RXXR, and the all the sequences in Table 5 share the same conserved consensus sequence of 5 amino acids. However, the sequences with SEQ ID NOS: 4 and 5 do not share or have the required

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convertase consensus RXXR, such that the assertion of that the peptides with SEQ ID NOS 4 and 5 are also transporter peptides. The specification does not have examples of the use of the compounds to translocate. Thus the invention lacks written description.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the transporter peptides are translocated across the membrane of pancreatic B-cells.

10. The following is a statement of reasons for the indication of allowable subject matter: The claimed method of translocating the transporter peptides of SEQ ID NOS: 1-6 is neither taught nor suggested by the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884.

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The examiner is on Flex Schedule and can normally be reached from Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

pp
28 September 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER